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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/084,587      | 02/25/2002  | Edward J. Gavin      | 016866-008200US     | 6008             |

20350 7590 05/25/2005

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| EXAMINER |
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LAU, TUNG S

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

2863

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |  |                     |  |
|------------------------------|------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> |  | <b>Applicant(s)</b> |  |
|                              | 10/084,587             |  | GAVIN ET AL.        |  |
|                              | <b>Examiner</b>        |  | <b>Art Unit</b>     |  |
|                              | Tung S. Lau            |  | 2863                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### Specification amendment

1. The Specification amendment filed on 4-27-2005 is noted and accepted by the examiner.

### Double Patenting rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-40 provisionally rejected under the judicially created doctrine of double patenting over claim 1-38 of copending Application No. 09999081. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: analyzes mass spectra using a digital computer, the method comprising: a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes, each class characterized by a different

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biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio; and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 35, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, 19, 30, 31, 32, 33, 34, 37, 38, 39, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Paulse et al (U.S. Patent Application Publication 2004/00599530).

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Regarding claim 1:

Paulse discloses a method that analyzes mass spectra using a digital computer, the method comprising: a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes (page 2, section 0012-0019), each class characterized by a different biological status (page 2, section 0012-0019), and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio (page 2, section 0012-0019) using laser ionization desorption process (page 2, section 0012-0019); and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process (page 2, section 0012-0019).

Regarding claim 35:

Paulse discloses a computer readable medium a) code for entering data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes (page 2, section 0012-0019), each class characterized by a different biological status (page 2, section 0012-0019), and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio (page 2,

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section 0012-0019) using laser ionization desorption process (page 2, section 0012-0019); and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process (page 2, section 0012-0019).

Regarding claims 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, 19, 30, 31, 32, 33, 34, 37, 38, 39, 40, 16, 20, 36:

Paulse also disclose the use of MALDI (page 5, section 0056), class consist of two classes (page 6, section 0061), selected from group of Polypeptides and nucleic acids (page 4, section 0044), selected from virus (page 13, claim 5), normal and pathological status (page 4, section 0048), un-diseased, low and high grade cancer (page 1, section 0003), use a drug treated state, drug-responder and non-responder state (page 5, section 0049), toxic and non toxic state (page 10, section 0098), exposure to drug (page 10, section 0097), is a known data set (page 3, section 0031), pre-existing marker from classification (page 1, section 0003), detecting signal of mass spectra in mass-to charge ratio (page 1, section 0004), identifying features and different biological status (page 2, section 0010), process is binary recursive partitioning process (page 2, section 0012), interrogating classification for biological statues, using larger sample (page 9, section 0090), use in a gas ion spectrometer (page 5, section 0055), adopted to perform a laser desorption ionization process (page 2, section 0015), a surface

enhance desorption with antibodies (page 5, section 0056). Using an unknown sample (page 7, section 0068); repeat process (page 9, section 0087); cluster analysis (page 1, section 0009); using unknown sample (page 7, section 0068); use of antibodies material (page 6, section 0061), function derived from mass to charge ratio (page 1, section 0004), use neural network analysis (page 4, section 0040), raw data processing (page 3, section 0039).

### ***Response to Arguments***

4. Applicant's arguments with respect to claim invention filed 04/27/2005 have been fully considered but they are not persuasive.

Applicant argue that Paulse et al (U.S. Patent Application Publication 2004/00599530) is not a prior art because on **7-16-2004** (according to PALM), filed claimed priority date of 11-16-2000, but MPEP 201.11 state that claiming benefit under 35 U.S.C. 119(e) and 120 for utility and plant patent applications filed on or after November 29,2000 claims for benefit under 35 U.S.C. 119(e), 120, 121 and 356(c) must be made during pendency of the application and within the latest of **4 months** from the actual date of the application or **16 months** from the filling date of the prior application 37 CFR 1.78(a)(2) and (a)(5). Since none of the above date was meet, therefore the priority date claimed (11-16-2000) is not valid, and the rejection stands (see MPEP 201.11).

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Note: the applicant claimed priority was filed on 11-13-2004, but USPTO PALM does not show it was the case, either case the date do not meet with this requirement.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S Lau whose telephone number is 571-272-2274. The examiner can normally be reached on M-F 9-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 571-272-2269. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TL

**BRYAN BUI**  
**PRIMARY EXAMINER**

*Bryan Bui*